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Daniel W. Collins
VP, Legal-Intellectual Property
CV Therapeutics, Inc.
3172 Porter Drive
Palo Alto, CA 94304

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,403,567

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,403,567, claims of which cover the human drug product LEXISCAN® (regadenoson monohydrate) and methods of using LEXISCAN® (regadenoson monohydrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,024 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,642,210 based on the regulatory review period for LEXISCAN® (regadenoson monohydrate).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 6,642,210, will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,403,567 for 1,024 days. In the absence of a request for reconsideration, and if U.S. Patent No. 6,403,567 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 1,024 days in U.S. Patent No. 6,403,567.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 24, 2009 (74 Fed. Reg. 42678) would be 1,232 days. Under 35 U.S.C. § 156(c):

$$\text{Period of Extension} = \text{RRP} - \text{PGRRP} - \text{DD} - \tfrac{1}{2}(\text{TP} - \text{PGTP})^{1}$$

[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on

= 2,446 - 315 - 0 - ½ (2,113- 315)
= 1,232 days (3.4 years)

Since the regulatory review period began August 1, 2001, before the patent issued (June 11, 2002), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 1, 2001, to and including June 11, 2002, is 315 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) Furthermore, the entire regulatory review period, 2.446 days, includes the pre-patent grant regulatory review time, so the entire regulatory review period must exclude any pre-patent grant days, thus, 315 days is subtracted from the entire regulatory review period. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,232 days, would extend the patent from June 21, 2019 to November 4, 2022, which is beyond the 14-year limit (the approval date is April 10, 2008, thus the 14 year limit is April 20, 2022, or 1,024 days). The period of extension is thus limited to 1,024 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 21, 2019, to and including April 10, 2022, or 1,024 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,403,567
Granted:	June 11, 2002
Original Expiration Date[2]:	June 21, 2019

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which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Applicant:	Jeff A. Zablocki et al.
Owner of Record:	CV Therapeutics, Inc.
Title:	N-Pyrazole A_{2A} Adenosine Receptor Agonists
Product Trade Name:	LEXISCAN® (regadenoson monohydrate)
Term Extended:	1,024 days
Expiration Date of Extension:	April 10, 2022

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: LEXISCAN® (regadenoson monohydrate)
Docket No.: FDA-2009-E-0048